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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,352	12/11/2003	Matt D. Pursley	PUR-020	3757

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EXAMINER	
BECK, DAVID THOMAS	

ART UNIT	PAPER NUMBER
1732	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,352	PURSLEY, MATT D.	
	Examiner	Art Unit	
	David T. Beck	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figures 1-4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-14, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarge et al (2001/0041881).

With regard to claim 1, Sarge et al teaches a method of making a catheter (abstract), comprising the steps of: winding a filament onto a core member while rotating the core member relative to a filament source and passing the filament source in a first direction of axial movement relative to the core member, and reversing a direction of axial movement of the filament source while continuing to wind the filament

onto the core member, whereby the filament is continuously wound onto the core member to form a first fibrous layer as the filament source is moved relative to the core member from a first axial position to a second axial position and then back to the first axial position (paragraph 0067).

With regard to claim 2, Sarge et al teaches anchoring the filament at or near a proximal end of the core member before winding the filament onto the core member (paragraph 0063).

With regard to claim 3, Sarge et al teaches the filament is wound onto the core member continuously from the proximal end of the core member to a distal end thereof and then back to the proximal end (paragraph 0065-0067; Figure 3).

With regard to claim 4, Sarge et al teaches winding the filament onto the core member comprises winding the filament with a variable pitch along a length of the core member such that a filament spacing at the distal end of the core member is narrower than a filament spacing at the proximal end of the core member (paragraph 0065-0067; Figure 3).

With regard to claim 5, Sarge et al teaches that the core member is a mandrel on which the catheter is formed (paragraph 0080).

With regard to claim 6, Sarge et al teaches that the core member is a substrate that forms an inner lining of the catheter (paragraph 0063).

With regard to claim 7, Sarge et al teaches that the filament source is a filament spool (paragraph 0069).

With regard to claim 8, Sarge et al teaches that the step of winding the filament onto the core member comprises winding the filament with a constant pitch along a length of the core member (paragraph 0066).

With regard to claim 9, Sarge et al teaches that the step of winding the filament onto the core member comprises winding the filament with a varied pitch along a length of the core member (paragraph 0066).

With regard to claim 10, Sarge et al teaches winding at least one additional layer of filament (paragraph 0068, third portion) over said first fibrous layer to form at least one additional fibrous layer (paragraph 0069; Figure 2).

With regard to claim 11, Sarge et al teaches continuously winding the filament over the first fibrous layer as the filament source is moved axially along the core member from a proximal position to a distal position and then back to the proximal position (paragraph 0069).

With regard to claim 12, Sarge et al teaches that said proximal position is at a proximal end of the core member and said distal position is between the proximal end and a distal end of the core member (Figure 4, number 84).

With regard to claim 13, Sarge et al teaches one additional fibrous layer comprises a plurality of additional fibrous layers (Figure 2, number 56), and wherein said plurality of additional fibrous layers extend to different distal positions along the core member, whereby the first and additional fibrous layers form a catheter having a tapering profile and variable properties along its length (Figure 2, number 62).

With regard to claim 14, Sarge et al teaches placing a marker band at a distal end of at least one of said fibrous layers (paragraph 0062; Figure 3, number 70).

With regard to claim 17, Sarge et al teaches coating the core member and fibrous layer with plastic (paragraph 0071, PTFE sleeve).

With regard to claim 19, Sarge et al teaches laminating a plastic tube over an outer surface of the core member and the fibrous layer (paragraph 0071-0072).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Jansen et al (2002/0156460).

With regard to claim 15, Sarge et al teaches the invention of claim 14, but fails to explicitly teach placing marker bands at the distal ends of a plurality of said fibrous layers. Jansen et al teaches placing marker bands at the distal ends of a plurality of said fibrous layers (column 12, lines 35-39; Figure 5, number 508). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to place marker bands at the distal ends of a plurality of fibrous layers in the method of Sarge et al. The motivation to do so would have been to depict ends of the various flexibility regions (Jansen et al, column 12, lines 35-39).

With regard to claim 16, Jansen et al teaches that marker band has a wall thickness approximately equal to the thickness of said distal end of the fibrous layer (Figure 5, number 508).

6. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Pursley (6,030,371).

With regard to claim 18, Sarge et al teaches the invention of claim 17, but fails to expressly teach applying a polymer material in a particulate preform over an outer surface of the core member and the fibrous layer. Pursley teaches applying a polymer material in a particulate preform over an outer surface of the core member and the fibrous layer (abstract). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to apply polymer material in a particulate preform to the wound catheter in the process taught by Sarge et al. The motivation to do so would have been to vary the composition of the polymer material continuously as it is being applied to provide a variable hardness over the length of the catheter (Pursley, abstract).

With regard to claim 21, Pursley teaches applying a molecular strand of plastic material over an outer surface of the core member and the fibrous layer using electrostatic forces (column 7, lines 7-24).

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Keith et al (5,888,436).

With regard to claim 20, Sarge et al teaches the invention of claim 17, but fails to

expressly teach extruding a plastic material over an outer surface of the core member and the fibrous layer. Keith et al teaches extruding a plastic material over an outer surface of the core member and the fibrous layer (column 4, lines 58-64). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to extrude a plastic material over the surface of the core member and the fibrous layer in the process taught by Sarge et al. The motivation to do so would have been to create a smooth surface composite or provide additional thickness that can be ground smooth (Keith, column 4, lines 56-59).

8. Claims 22-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Klint (2001/0044633).

With regard to claim 22, Sarge et al teaches the invention of claim 1, but does not explicitly teach winding a group of filaments simultaneously. Klint teaches winding a group of filaments simultaneously (paragraph 0015). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to wind a group of filaments simultaneously in the process taught by Sarge et al. The motivation to do so would have been to promote the uniform and well-defined characteristics along the length of the catheter (Klint, paragraph 0065).

With regard to claim 23, Klint teaches that the group of filaments is wound with a constant spacing between the filaments within the group (Figure 7).

With regard to claim 24, Klint teaches that the group of filaments is wound with a variable pitch such that a filament group spacing at a distal end of the core member is

narrower than a filament group spacing at a proximal end of the core member (paragraph 0020, reducing the number of wires changes the spacing).

With regard to claim 25, Klint teaches that filaments are wound with a variable spacing between the filaments within the group such that a filament spacing at a distal end of the core member is narrower than a filament spacing at a proximal end of the core member (paragraph 0020, reducing the number of wires changes the spacing).

With regard to claim 26, Klint teaches that the group of filaments is wound with a variable pitch and a variable spacing between the filaments within the filament group (paragraph 0020, reducing the number of wires changes the spacing).

With regard to claim 28, Klint teaches providing a guide assembly having a filament engaging surface, and arranging said guide assembly such that the filament engaging surface lies in a plane which is generally perpendicular to a longitudinal axis of the core member, whereby the guide assembly causes the filaments within said group of filaments to be positioned side-by-side and packed tightly against one another as the group of filaments are wound onto the core member (paragraph 0048). Klint teaches "placing a group of from two to twelve wires of desired wire diameter in a row next to or closely adjacent to each other." The group must necessarily be placed onto an assembly of some sort to facilitate the unwinding of the filaments and the assembly must have guides to keep the wires closely packed.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Klint (2001/0044633) and Itou et al (6,511,462).

With regard to claim 27, Sarge et al in view of Klint teaches the invention of claim

22, but fails to expressly teach using wire guides to control the filament spacing within the group of filaments, and varying a spacing between the wire guides as the winding proceeds along a length of the core member. Itou et al teaches using wire guides to control the filament spacing within the group of filaments, and varying a spacing between the wire guides as the winding proceeds along a length of the core member (column 2, lines 45-52). Itou et al changes the spacing between the wire guides by adjusting their relative rotating speeds and thus controls the filament spacing within the group of filaments. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to varying a spacing between the wire guides as the winding proceeds along a length of the core member as taught by Itou et al in the process taught by Sarge et al in view of Klint. The motivation to do so would have been to create a first linear member with a flexural rigidity higher than that of the second linear member (Itou et al, column 2, lines 53-55).

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Klint (2001/0044633) and McMickle et al (4,484,586).

With regard to claim 29, Sarge et al in view of Klint teaches the invention of claim 28, and teaches varying a pitch of the group of filaments being wound onto the core member (Sarge et al, paragraph 0067), but does not explicitly teach varying a rotation speed of the core member or a translation speed of the filament source along the core member. McMickle teaches varying the pitch by changing the rotation speed in relation to the translation speed (column 2, lines 45-47). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to vary the pitch in the process

taught by Sarge et al by changing the rotation speed in relation to the translation speed. The motivation to do so would have been to form a length of tubing with varying degrees of flexibility along its length (McMickle et al, column 2, lines 47-50).

11. Claims 30, 32-34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klint (2001/0044633) in view of Sarge et al (2001/0041881).

With regard to claim 30, Klint teaches a method of making a catheter (abstract), comprising the step of winding a group of filaments simultaneously onto a core member (paragraph 0015) but does not expressly teach rotating the core member relative to a source of said filaments and passing the source of filaments in a first direction of axial movement relative to the core member. Sarge et al teaches rotating the core member relative to a source of said filaments and passing the source of filaments in a first direction of axial movement relative to the core member (paragraph 0067). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to wind the filaments in the process taught by Klint by rotating the core member and passing the filaments in a first direction as taught by Sarge et al. The motivation to do so would have been to wind the filaments at different pitches (Sarge et al, paragraph 0066).

With regard to claim 32, Klint teaches that the group of filaments is wound with a variable pitch such that a filament group spacing at a distal end of the core member is narrower than a filament group spacing at a proximal end of the core member (paragraph 0050).

With regard to claim 33, Klint teaches that group of filaments is wound with a variable spacing between the filaments within the group such that a filament spacing at a distal end of the core member is narrower than a filament spacing at a proximal end of the core member (paragraph 0020, reducing the number of wires changes the spacing).

With regard to claim 34, Klint teaches that the group of filaments is wound with a variable pitch and a variable spacing between the filaments within the filament group (paragraph 0020, reducing the number of wires changes the spacing).

With regard to claim 36, Klint teaches providing a guide assembly having a filament engaging surface, and arranging said guide assembly such that the filament engaging surface lies in a plane which is generally perpendicular to a longitudinal axis of the core member, whereby the guide assembly causes the filaments within said group of filaments to be positioned side-by-side and packed tightly against one another as the group of filaments are wound onto the core member (paragraph 0048). Klint teaches "placing a group of from two to twelve wires of desired wire diameter in a row next to or closely adjacent to each other." The group must necessarily be placed onto an assembly of some sort to facilitate the unwinding of the filaments and the assembly must have guides to keep the wires closely packed.

With regard to claim 37, Sarge et al teaches reversing a direction of axial movement of the source of filaments relative to the core member while continuing to wind the group of filaments onto the core member, whereby the filaments are continuously wound onto the core member as the source of filaments is moved relative to the core member from a first axial position to a second axial position and then back to

the first axial position (paragraph 0068). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to move source of filaments relative to the core member from a first axial position to a second axial position and then back to the first axial position. The motivation to do so would have been to form two layers of filaments to build a catheter having two or more discrete tubular members having different performance characteristics (Sarge et al, paragraph 0011).

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klint (2001/0044633) in view of Sarge et al (2001/0041881) and McMickle et al (4,484,586).

With regard to claim 31, Klint in view of Sarge et al teaches the invention of claim 30, and teaches varying a pitch of the group of filaments being wound onto the core member (Klint, paragraph 0020), but does not explicitly teach varying a rotation speed of the core member or a translation speed of the filament source along the core member. McMickle teaches varying the pitch by changing the rotation speed in relation to the translation speed (column 2, lines 45-47). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to vary the pitch in the process taught by Klint by changing the rotation speed in relation to the translation speed. The motivation to do so would have been to form a length of tubing with varying degrees of flexibility along its length (McMickle et al, column 2, lines 47-50).

13. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klint (2001/0044633) in view of Sarge et al (2001/0041881) and Itou et al (6,511,462).

With regard to claim 35, Klint in view of Sarge et al teaches the invention of claim

30, but fails to expressly teach using wire guides to control the filament spacing within the group of filaments, and varying a spacing between the wire guides as the winding proceeds along a length of the core member. Itou et al teaches using wire guides to control the filament spacing within the group of filaments, and varying a spacing between the wire guides as the winding proceeds along a length of the core member (column 2, lines 45-52). Itou et al changes the spacing between the wire guides by adjusting their relative rotating speeds and thus controls the filament spacing within the group of filaments. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to varying a spacing between the wire guides as the winding proceeds along a length of the core member as taught by Itou et al in the process taught by Klint in view of Sarge et al. The motivation to do so would have been to create a first linear member with a flexural rigidity higher than that of the second linear member (Itou et al, column 2, lines 53-55).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Beck whose telephone number is 571-272-2942. The examiner can normally be reached on Monday - Friday, 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 517-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DTB
January 18, 2005

DTB

MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER